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EXAMINER	
CUTLIFF, YATE KAI RENE	

ART UNIT	PAPER NUMBER
1621	

NOTIFICATION DATE	DELIVERY MODE
08/04/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/511,829	SUMIDA ET AL.	
	Examiner	Art Unit	
	YATE' K. CUTLIFF	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 8 - 21 & 28 - 35* is/are pending in the application.

4a) Of the above claim(s) *8 - 14, 19, 20 & 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 15 - 18, 21 & 29 - 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 March 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1, 8 - 21 & 28 - 35, 5, 7, 15-18, 21, 24-27 and 29-32 are pending.

Claims 2 – 7 and 22-27 have been canceled

Claims 8-14, 19, 20 and 28 have been withdrawn.

Claims 1, 15 – 18, 21 and 29 - 35 are rejected.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 25, 2010 has been entered.

Response to Arguments

3. Applicant's arguments, see pages 6 - 9, filed June 25, 2010, with respect to the rejection(s) of claim(s) 4, 5, 21 and 24 under 35 USC 103(a) have been fully considered and are persuasive in view of the cancelation of the claims 4, 5, 21 and 27. Therefore, the rejection has been withdrawn. However, Applicant's arguments with respect to the USC 35 103(a) rejections of claims 1, 15 – 18, 21 & 29 - 35 have been fully considered and are not persuasive for the reasons set out in the Office Action mailed December 28, 2009; and the reasons set out below.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 15 – 18, 21 and 29 - 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuniaki, et al. (JP 01-202261, English translation), Yukihisa et al. (JP 11-290094, English translation) and Kleinig (Univ. Heidelberg, 1967, abstract); for the

reasons set out in the Office Action mailed September 2, 2009; and obvious in view of Kuniaki et al, Yukihisa et al. and Kleinig and further in view of Babayan et al. (US 3,450,819) as set out below.

8. Rejected claim 1 covers a purified astaxanthin medium-chain fatty acid ester, wherein the medium-chain fatty acid ester is a monoester, and wherein the medium-chain fatty acid has 8 carbon atoms. Rejected claims 15 – 18, 21 and 28 - 35 cover, inter alia, a food composition, a food additive, a cosmetic, an animal feed or a composition containing at least 0.1% of astaxanthin medium chain fatty acid ester.

9. Kuniaki et al. discloses a process for preparing esters of astaxanthin using a conventional method of esterifying alcohols, wherein the hydroxyl group of the astaxanthin is esterified with higher or lower fatty acids. (see abstract). According to the teaching of Kuniaki et al. this is done to stabilize the astaxanthin. Kuniaki et al. states that esterifying a hydroxy group of astaxanthin with fatty acid remarkably improves the stability of the astaxanthin. (see page 2, para. 4). Also, it is stated that fatty acid esters of astaxanthin are known compounds and that conventional methods to conduct esterification of alcohols can be used. (see page 3, para. 4). Further, in Example 3 of the process caproic acid (C6:0) was used in the reaction process. The process of Kuniaki et al. produced esters of astaxanthin that were used as an additive to feed for fish. (see page 2 para. 5).

10. The difference between Kuniaki et al. and Applicant's claimed invention is as follows: astaxanthin ester being a monoester of a medium chain fatty acid with 8 carbon

atoms; the use of the monoester as food composition by mixing with food, and use of the monoester with a cosmetic composition.

11. However, with regard to the differences set out above the Examiner turns to the combined teachings of Kuniaki et al, Ykihisa et al. and Kleinig, in view of Babayan et al.

Yukihisa et al. discloses a process for preparing fatty acid monoesters of astaxanthin in an esterification reaction with fatty acids having 14 to 22 carbon atoms and lipase. (see [0001 & [0008], para. (1)). The esters produced can be used for food, and cosmetics. (see [0004]). It is stated that monoesters of astaxanthin is more stable than free astaxanthin and have superior absorption efficiency in the enteric canal (The gut; a tube concerned with digestion and absorption of food. In most animals it has one opening (mouth) into which food is taken and another (anus) from which unassimilated material is rejected.). (see page 8, [0005]). Further, in the reaction process of Yukihisa et al. it is suggested that the ratio of fatty acid to free astaxanthin is less than 2 times mole, a high content of fatty acid diesters cannot be attained. (see [0013]). Also, in the process as set out in Examples 1-9 as reported in Table 2, each time the lapse esterification with the selected fatty acids is conducted, a mixture containing monoester and diester are produced. One of ordinary skill in the art would reasonably expect that based in the process taught by Yukihisa, that when the fatty acid to free astaxanthin ratio is out side of 2 to 20 (1:10) or 5 to 10 (1:2) that the reaction mixtures would have a higher monoester yields. (see [0013]) This conclusion is supported by Yukihisa's Table 2 Example 3. In that reaction the ratio of fatty acid to astaxanthin was 1:5 and the level of monoester after 24 hours was higher than the level of diester produced.

Furthermore, according to the teaching of Yukihisa et al. the fatty acid monoester produced by their reaction can be removed from the product mixture by HPLC (see Example 10). Thus, even though Yukihisa et al. has a preference for long chain fatty acid esters of astaxanthin, it broadly teaches a process for the production of fatty acid esters of astaxanthin.

Kleinig discloses that the medium chain fatty acid, capric acid (C10) can be esterified with astaxanthin. (see page 4, para. 2, not #2).

The Yukihisa's reference does not specifically teach the use of fatty acids with C8 carbon atoms in their esterification process, but from the combined teachings of Kuniaki et al. and Yukihisa et al. one of ordinary skill in the art would reasonably expect that any conventional method used to esterify alcohols and fatty acids could be used to esterify the hydroxyl group of astaxanthin with medium-chain fatty acid than has 8 carbon atoms. Especially in light of the fact that astaxanthin esters can be produced with a C6 fatty acid as taught by Kuniaki and a C10 fatty acid as suggested by Kleinig, both of which are medium chain fatty acid according to the teaching of Babayan would recognize that the C6 fatty acid (caproic acid) is medium chain fatty acids. (see col. 2 lines 53 – 57).

The difference between the combinations of the references of Kuniaki, et al., Yukihisa et al. and Kleinig is that the monoester of astaxanthin has C8 carbon atoms. However, the C8 (caprylic) fatty acid is between the caproic (C6) fatty acid used in the reaction process of Kuniaki et al. and the capric (C10) used in the esterification process of Kleinig, and each of these fatty acid are known to one having ordinary skill in the art

to be medium chain fatty acids. Thus, based on the teachings of these references, one of ordinary skill in the art would expect that a caprylic acid (C8) could be substituted in any of the esterification reactions of Kuniaki, et al., Yukihisa et al. or Kleinig and produce a C8 monoester of astaxanthin. Therefore, the preparation of a fatty acid monoester of astaxanthin wherein the fatty acid has C8 carbon atoms can be affected via routine experimentation by the ordinary artesian skilled in the art. When the general condition of a claim are disclosed in the prior art, it is not inventive to discover optimum of workable ranges by routine experimentation. In re Aller, 220 F.@D 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Examiner's Response to Applicant's Arguments

12. Applicant respectfully asserts *Yukihisa* fails to disclose an astaxanthin medium-chain fatty acid monoester having 8 carbon atoms. Further, as asserted previously, the method of producing astaxanthin esters disclosed in *Yukihisa* does not produce the claimed astaxanthin ester, at least because *Yukihisa* fails to, and specifically teaches away from, adding water to the reaction system beyond what was retained by vacuum-dried lipases. Specifically, *Yukihisa* discloses the following:

"Since the reaction in the present invention is a reversible equilibrium reaction, water which generates with progress of the reaction will be a factor which inhibits the reaction. As for the water content at the time of the reaction, 200 ppm to 1000 ppm is desirable in the present invention. When the water content is more than 1000 ppm, main reaction shifts from synthetic reaction to decomposition reaction and the purity of the astaxanthin fatty acid diesters is lowered and accordingly such a

content is not preferable. When the water content is less than 200 ppm, hydration water which lipases have for stability will be removed, leading to inactivation of lipases and accordingly such a content is not preferable." *See, e.g.,* p. 13, para. 18 of the English Translation.

Further, Applicant states that the water present in the system of *Yukihisa* is not separately added to the system. *See, e.g.,* Examples 1-10 of *Yukihisa.* The water content that is described in *Yukihisa* is obtained from the addition of vacuum-dried lipases into the reaction system, wherein the lipases retain a small amount of water.

13. In response, the Examiner reviews the above comments and Applicant's efforts to show that their process when compared to the process of Yukihisa, is able to produce monoesters, while the process of Yukihisa would not have been able to produce the monoester and teaches away from the claimed invention. However, the Examiner's understand is that even though Yukihisa teaches that there is a preference for using water in amounts of 200 ppm to 1000 ppm it does not teach that the reaction will not occur. Yukihisa, only teaches that at the higher water content the reaction shifts and causes the purity level of the astaxanthin fatty acid diester to become lower. A preference is not a teaching away because it does not discourage the use of water it only discloses a preference for a limited amount of water in the reaction.

14. Furthermore, Applicant discusses that their process uses a similar vacuum-dried lipases with small amounts of water, and then separately adds additional water to the reaction system to produce astaxanthin medium chain fatty acid monoester with the medium chain having 8 carbon atoms. In particular in Table 1 on page 8 of the instant

Specification, 0 water % refers to no separately added water in the system, but it does include small amounts of water added only with the dried enzyme. Thus, the water content in a reaction system of *Yukihisa,* where no separately added water is present, corresponds to the reaction system of 0 water % condition in Table 1 on page 8 of the instant Specification. *See, e.g.,* p. 8, 1.5-20. The results of 0 water % condition in Table 1 shows that the method, which is similar to *Yukihisa,* produces no detectable amount of astaxanthin octanoic acid monoester. *See, e.g.,* p. 8, 11. 17-20. Finally, asserting that this information that is provided in the instant specification is sufficient evidence that no astaxanthin octanoic acid monoester was formed or could have been formed by the process of *Yukihisa.*

15. In response, the Examiner notes that Applicant is asserting that their 0 water % condition of Table 1 is equivalent to Yukihisa's process which adds no additional water. The Examiner notes that even though Yukihisa's process does not add additional water, there is water in the reaction system, and it teaches that the water can be no lower than 200 ppm. Further, Applicant's discussion of Table 1 in their specification lists the water percent in the reaction as 0%, one having ordinary skill in the art reading the Specification and Table 1 could reasonably presume that Applicant's process is demonstrating the reaction without water. Applicant has merely shown that a reaction taking place without water will not yield the desired octanoic monoester of astaxanthin. The next water level in Applicant's process is 1%, which is above the preferred amount of water of 1000 ppm of Yukihisa's process. At the 1% water level the octanoic acid ester of astaxanthin is produced. Applicant has not demonstrated that the monoester

cannot be produced when water is within the reaction system at the ranges taught by Yukihisa. As such Applicant's disclosure in the Specification is not a reasonable comparison with the closest prior art.

16. Applicant respectfully asserts that because no astaxanthin medium chain fatty acid monoester having 8 carbon atoms is produced in the method of Yukihisa, the allegation that Applicant has not provided information on the levels of purity is moot. Further asserting that Applicant does not need to provide information on the levels of purity to distinguish from Yukihisa, at least because Yukihisa produces no astaxanthin medium chain fatty acid monoester having 8 carbon atoms at any purity level.

17. In response, the Examiner states the factors to be considered in determining whether a purified form of an old product is obvious over the prior art include whether **the claimed chemical compound or composition has the same utility as closely related materials in the prior art, and whether the prior art suggests** the particular form or structure of the claimed material or **suitable methods of obtaining that form or structure**. (In re Cofer, 354 F.2d 664, 148 USPQ 268 (CCPA 1966)). Furthermore, when claiming a purer form of a known compound, it must be demonstrated that the purified material posses properties and utilities not possessed by the unpurified material. (Ex parte Reed, 135 USPQ 34, 36 (Bd. Pat. App. & Int. 1961). In this instance the references Kuniaki, et al. and Yukihisa et al. disclose conventional methods for preparing monoesters of astaxanthin using fatty acid esters at different ends of a homologous series of fatty acids (i.e. C6 (medium chain) and C14 (long chain)); with Kleinig using a C10 (medium chain) fatty acid to esterify the astaxanthin.

Both of the references of Kuniaki, et al. and Yukihisa et al. disclose the fact that esters of astaxanthin are suitable for use in food. Yukihisa et al. discloses that fatty acid esters of astaxanthin are suitable for use in cosmetics. Thus, one of ordinary skill in the art at the time of Applicant's claimed inventions would expect that monoesters of astaxanthin of medium-chain fatty acids (C8) possess the same or similar properties as any close homologs of the series.

An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties. Where prior art compounds essentially bracket the claimed compounds and are well known pesticides, one of ordinary skill in the art would be motivated to make the claimed compounds in searching for new pesticides. (In re Payne, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979). In this instance, the references of Kuniaki, et al., Yukihisa et al. and Kleinig discloses esters that bracket the monoesters of Applicant's claimed compound.

Therefore, the invention as a whole was *prima facie* obvious because a person of ordinary skill in the art at the time the invention was made, would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success.

18. Applicant respectfully requested rejoinder of the withdrawn claims upon allowance of the article or compound/composition claims.

19. In response, the Examiner states that once allowable subject matter is found the withdrawn claim will be rejoined and fully examined for patentability under 37 CFR 1.104. However, at this time the article or compound/composition claims remain rejected. Furthermore, the Examiner made a cursory review of the process claims and noted that the amount of water added as set out in the claims is 0.5%, while Table 1 shows 1% as the lowest amount of water used in Applicant's process.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YATE' K. CUTLIFF whose telephone number is (571)272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on (571) 272 - 0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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